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Number of Papers in This Submission

Application Number	08/846,658
Filing Date	May 1, 1997
First Named Inventor	John R. Adair et al.
Art Unit	1642
Examiner Name	Minh Tam B. Davis

One

Attorney Docket Number

CARP0001-100

ENCLOSURES (check all that apply)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	Cozen O'Connor, P.C.		
Signature	<i>Doreen Yatko Trujillo</i>		
Printed Name	Doreen Yatko Trujillo		
Date	January 22, 2007	Reg. No.	35,719

CERTIFICATE OF TRANSMISSION/MAILING

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Signature	<i>Doreen Yatko Trujillo</i>		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Adair et al.

Confirmation No. 9631

Serial No.: 08/846,658

Art Unit No.: 1642

Filing Date: May 1, 1997

Examiner: Minh Tam B. Davis

For: **HUMANISED ANTIBODIES**

Customer No.: 34132

Docket No.: CARP0001-100

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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

REPLY BRIEF UNDER 37 CFR § 41.41

This Reply Brief is being filed in response to the Examiner's Answer dated as mailed November 20, 2006. Appellants have a non-extendable two-month period of time to file a Reply Brief, or January 20, 2007. As January 20, 2007 fell on a Saturday, this Reply Brief is timely filed on Monday, January 22, 2007.

Preliminarily, Appellants thank the Office for granting Appellants' request to use the Evidence Appendices filed with the Appeal Brief filed on February 14, 2005. Appellants' also thank the Office for noting the correct parent GB application number, and for acknowledging that the status of the amendments is correct, and that the copy of appealed claims is correct. Appellants also note that the Office acknowledged that the statement of the grounds of rejection to be reviewed upon appeal is also correct. Appellants are somewhat perplexed, however, by the Office's observation that the statement of the status of the claims is only "substantially correct."

All pending claims, per Appellants' understanding, are rejected. Appellants are proceeding on the assumption that the Office's language here is precautionary, as opposed to an indication of an error in the status of the claims.

RESPONSE TO ARGUMENTS IN EXAMINER'S ANSWER

In their Appeal Brief filed on June 2, 2006, Appellants challenged the appropriateness of the Office's reopening of prosecution following the filing of their Appeal Brief on February 14, 2005. In the Examiner's Answer, the Office responded by stating that the reopening was necessary to change the rejection from one under 35 USC 102(e) to one under 35 USC 102(e)/103, and to expand the reasons for rejection under 35 USC 102(e)/103. The Office also referred to the citation of the Winter reference and the Lohmeyer reference. As Appellants argued in the Appeal Brief filed June 2, 2006, however, the references cited by the Office were merely cumulative and, thus, did not merit reopening of prosecution. And, the changing of the rejection seems completely unnecessary considering that Appellants **copied** the claims of Queen et al with the goal of provoking an interference. Accordingly, Appellants maintain that the Office should not be allowed to change the rejection and add these references at this late stage in prosecution. Nonetheless, Appellants submit the following response to the Examiner's Answer.

The Office makes several errors in the Examiner's Answer. First, the Office argues that what occurred in other of Queen's applications is not germane because each case is decided on its own facts and it is "well settled that whether similar claims have been allowed to **others** is immaterial." (See, for example, page 18 of the Examiner's Answer, first and third full paragraphs, emphasis added.) Appellants' arguments are not based upon what occurred in the application of **another**; Appellants' arguments are based upon what occurred in the prior and present applications of Queen et al. Because Queen et al has several continuation-in-part

applications in its priority chain, it must be shown that the claims, as issued, find support in those priority documents for Queen et al to be a reference as of those priority dates under 35 USC 102(e). *In re Wertheim*, 646 F.2d 527, 537, 209 USPQ 554, 564 (CCPA 1981). To determine whether or not there is support, the claims must be interpreted. What happened earlier in prosecution is relevant to an interpretation of the Queen et al claims. See *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1349, 69 USPQ2D 1815, 1823 (Fed. Cir. 2004), citing *Jonsson v. Stanley Works*, 903 F.2d 812, 818, 14 USPQ2d 1863, 1869 (Fed. Cir. 1990). Thus, the Office's continued disregard of what occurred earlier in prosecution in Queen et al is erroneous.

Second, the Office continues to misapprehend and misapply the law regarding the recitations "an affinity constant of at least 10^7 M^{-1} ," and "no greater than about four-fold that of the donor immunoglobulin" in the issued claims of Queen et al. Appellants arguments are that Queen et al is not entitled to its earliest effective filing dates under 35 USC 102(e) because there is no support for these limitations in those priority applications. That these limitations are not found in Appellants claims is **totally irrelevant** to the analysis of whether or not Queen et al is entitled to its earliest priority dates under 35 USC 102(e). Under *Wertheim, supra*, **the burden is upon the Office** to show that the priority applications can support these limitations. See MPEP 2136.03¹, Section IV. For the Office's convenience, the relevant portion is duplicated below.

¹ Appellants note that the Appeal Brief filed June 2, 2006 referred to the MPEP section as 2163.03, not 2136.03. This erroneous citation, however, does not explain the Office's misapplication of the law, i.e., *Wertheim*.

IV. PARENT'S FILING DATE WHEN REFERENCE IS A CONTINUATION-IN-PART OF THE PARENT

Filing Date of U.S. Parent Application **Can Only Be Used** as the
35 U.S.C. 102(e) Date If It Supports the Claims of the Issued Child

In order to carry back the 35 U.S.C. 102(e) critical date of the U.S. patent reference to the filing date of a parent application, the ~~>U.S. patent reference<~~ must * have a right of priority to the earlier date under 35 U.S.C. 120 or 365(c) and *~~>~~the parent application must< support the invention claimed as required by 35 U.S.C. 112, first paragraph. "For if a patent could not theoretically have issued the day the application was filed, it is not entitled to be used against another as 'secret prior art'" under 35 U.S.C. 102(e). *In re Wertheim*, 646 F.2d 527, 537, 209 USPQ 554, 564 (CCPA 1981) (The examiner made a 35 U.S.C. 103 rejection over a U.S. patent to Pfluger. The Pfluger patent (Pfluger IV) was the child of a string of abandoned parent applications (Pfluger I, the first application, Pfluger II and III, both CIPs). Pfluger IV was a continuation of Pfluger III. The court characterized the contents of the applications as follows: Pfluger I - subject matter A, II-AB, III-ABC, IV-ABC. ABC anticipated the claims of the examined application, but the filing date of III was later than the application filing date. So the examiner reached back to "A" in Pfluger I and combined this disclosure with another reference to establish obviousness. The court held that the examiner impermissibly carried over "A" and should have instead determined which of the parent applications contained the subject matter which made Pfluger patentable.

Only if B and C were not claimed, or at least not critical to the patentability of Pfluger IV, could the filing date of Pfluger I be used. The court reversed the rejection based on a determination that Pfluger IV was only entitled to the Pfluger III filing date. The added new matter (C) was critical to the claims of the issued patent.). Note that *In re Wertheim* modified the holding of *In re Lund*, 376 F.2d 982, 153 USPQ 625 (CCPA 1967) as to "carrying back" the subject matter to the parent applications.

MPEP 2136.03, Section IV, bold emphasis added.

Third, the Office mistakenly equates the determination of whether or not Queen et al is entitled to priority as a reference under 35 USC 102(e) with a determination of whether or not Queen et al is valid and states, thus, that such is not an issue for the Examiner to decide (see page 13 of the Examiner's Answer). The two determinations, however, are not equal. The acknowledgement that Queen et al may not be entitled to its priority date is not an allegation that it is invalid. Regardless, the Office should either argue that Queen et al is entitled to its earliest priority dates (which it has not done, nor can it do so) or withdraw the rejection. MPEP 2136.03.

Finally, the Office is misapplying the law of inherency. In justifying its arguments that Queen et al teaches the limitation that the donor amino acids must be "outside the Kabat and Chothia CDRS," the Office argues that several of the residues are inherently outside both the Kabat and Chothia CDRs. See, for example, the discussions on pages 6 through page 9 of the Examiner's Answer. But Queen et al describes making other residues donor that fall within the Kabat and Chothia CDRs. Accordingly, the requirements for inherency are not met.

To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference,

and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

In view of the foregoing, Appellants respectfully request that the Office withdraw the rejection over Queen et al under 35 USC 102(e)/103 and declare an interference.

Respectfully submitted,

Date: *January 22, 2007*

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